

CLAIM SUMMARY DOCUMENT

1. (Currently Amended) A topically applicable cosmetic/pharmaceutical oil-in-water emulsion [including] comprising a discontinuous fatty phase dispersed in a continuous aqueous phase and further comprising an effective amount of at least one biologically active agent (A) and an effective amount of an emulsifying system (B), wherein [therefor,] said at least one biologically active agent (A) is [being non-solubilized therein] in micronized particulate state and is non-solubilized in said emulsion, at least 80%, numerically, of said micronized particles have [having] diameters ranging from 1 to 10 μm , and at least 50%, also numerically, of said micronized particles have [having] diameters of less than 5 μm , and further wherein said at least one biologically active agent (A) comprises an agent which modulates skin differentiation and/or proliferation and/or pigmentation, an antibacterial agent, an antiparasitic agent, an antifungal agent, an antibiotic, a steroidal anti-inflammatory agent, a non-steroidal anti-inflammatory agent, an anaesthetic, an anti-pruriginous agent, an antiviral agent, a keratolytic agent, a free-radical scavenger, an antiseborrhoeic agent, an antidandruff agent, an anti-acne agent, an antimetabolite, an agent for combating hair loss and for promoting hair growth or vice versa, an antiseptic, or mixture thereof.

2. (Currently Amended) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, wherein at least 90%, numerically, of said micronized particles have [having] diameters ranging from 1 to 10 μm .

3. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said emulsifying system (B) comprising at least one copolymerizate of a major amount of a monoolefinically unsaturated C₃-C₆ carboxylic acid monomer, or anhydride thereof, with a minor amount of an acrylic acid fatty ester comonomer.

4. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, said emulsifying system (B) comprising at least one copolymerizate of 80% to 98% by weight of said monoolefinically unsaturated C₃-C₆ carboxylic acid monomer, or anhydride thereof, with 20% to 2% by weight of an acrylic acid fatty ester comonomer.

5. Withdrawn.

6. Withdrawn.

7. Withdrawn.

8. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, said at least one copolymerizate comprising an acrylic/C₁₀-C₃₀-alkylacrylate copolymer.

9. (Currently Amended) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 8, comprising from 0.05% to 2% by weight of said acrylic/C₁₀-C₃₀= alkylacrylate copolymer.

10. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 3, comprising from 0.01% to 3% by weight of said at least one copolymerizate.

11. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one surfactant emulsifier.

12. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 11, said at least one surfactant emulsifier comprising glyceryl or PEG-100 stearate, a polyoxyethylenated fatty acid ester, a polyoxyethylenated stearyl alcohol (2) combined with a polyethylenated stearyl alcohol (21), or mixture thereof.

13. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 11, further comprising at least one co-surfactant.

14. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 13, said at least one co-surfactant comprising a sorbitan ester, sorbitan

sesquioleate, sorbitan isostearate, a fatty alkyl ether having a high HLB value, a fatty alkyl ether having a low HLB value, or mixture thereof.

15. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising up to 15% by weight of said emulsifying system (B).

16. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 15, comprising from 0.05% to 8% by weight of said emulsifying system (B).

17. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 16, comprising from 0.1% to 2% by weight of said emulsifying system (B).

18. (Currently Amended) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said at least one biologically active agent (A) being insoluble [or difficultly soluble] in water or a hydrophilic medium under pH conditions which are compatible with the skin.

19. Canceled.

20. (Currently Amended) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1 [19], comprising from 0.0001% to 20% by weight of said at least one biologically active agent (A).

21. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 20, comprising from 0.025% to 15% by weight of said at least one biologically active agent (A).

22. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising from 5% to 50% by weight of said discontinuous fatty phase.

23. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 22, comprising from 12% to 25% by weight of said at least one discontinuous fatty phase.

24. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a silicone fatty substance.

25. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 24, said silicone fatty substance comprising a poly(C₁-C₂₀)alkylsiloxane or one containing trimethylsilyl endgroups, a linear polydimethylsiloxane, an

alkylmethylpolysiloxane, cetyltrimethicone, a volatile silicone oil, a cyclic volatile silicone having from 3 to 8 silicon atoms, a cyclomethicone, cyclotetradimethylsiloxane, cyclopentadimethylsiloxane, cyclohexadimethylsiloxane, a cyclocopolymer, a dimethylsiloxane/methylalkylsiloxane, a linear volatile silicone having from 2 to 9 silicon atoms, hexamethyldisiloxane, hexyl heptamethyltrisiloxane, octyl heptamethyltrisiloxane, a phenylsilicone oil, or mixture thereof.

26. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a non-silicone fatty oil, isohexadecane, a liquid paraffin, a liquid petroleum jelly, almond oil, perhydrosqualene, apricot oil, wheat germ oil, sweet almond oil, beauty-leaf oil, palm oil, castor oil, avocado oil, jojoba oil, olive oil, cereal germ oil, an ester of fatty acid or of a fatty alcohol, diisopropyl adipate, octyldodecyl myristate, a (C₁₂-C₁₅)alkyl benzoate, an acetyl glyceride, an alkyl or polyalkyl octanoate, a decanoate or ricinoleate, a fatty acid triglyceride, a glyceride, a hydrogenated polyisobutene, a hydrogenated oil that is solid at 25°C, a lanolin, a fatty ester that is solid at 25°C, or mixture thereof.

27. (Currently Amended) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, said discontinuous fatty phase comprising a fatty acid or fatty alcohol, esters [or derivative] thereof, a wax, or mixture thereof.

28. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, comprising from 30% to 95% by weight of said continuous aqueous phase.

29. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 28, comprising from 60% to 80% by weight of said continuous aqueous phase.

30. Withdrawn.

31. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one wetting agent.

32. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, said at least one wetting agent comprising a poloxamer, an oxyethylenated sorbitol ester, a polysorbate, or mixture thereof.

33. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, comprising from 01.% to 10% by weight of said at least one wetting agent.

34. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 31, further comprising at least one pro-penetrating and/or wetting agent.

35. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 34, said at least one pro-penetrating and/or wetting agent comprising propylene glycol, glycerol, sorbitol, or mixture thereof.

36. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 34, comprising from 1% to 20% by weight of said at least one pro-penetrating and/or wetting agent.

37. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one gelling agent.

38. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 37, said at least one gelling agent a carboxyvinyl polymer, a cellulose derivative, a xanthan gum, a guar gum, a polyacrylamide, or mixture thereof.

39. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 37, comprising from 0.05% to 5% by weight of said at least one gelling agent.

40. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, further comprising at least one sequestering agent, antioxidant, sunscreen, preservative, filler, dye or colorant, fragrance, essential oil, cosmetic active agent, moisturizer, vitamin, essential fatty acid, sphingolipid, artificial tanning agent, agent for soothing and protecting the skin, or mixture thereof.

41. (Currently Amended) A regime or regimen:

- (1) for treating dermatological conditions/afflictions associated with a keratinization disorder related to differentiation and proliferation, or
- (2) for treating another keratinization disorder, or
- (3) for treating another dermatological condition/affliction associated with a keratinization disorder manifesting an inflammatory and/or immunoallergenic component, or for treating inflammatory conditions which manifest no keratinization disorder, or
- (4) for treating all dermal or epidermal proliferations, whether benign or malignant and whether of viral or non-viral origin, or
- (5) for treating bullosis or a collagen disease state, or
- (6) for repairing or combating aging of the skin, whether photoinduced or chronological aging, or for reducing pigmentations and actinic keratosis, or any pathology associated with chronological or actinic aging, or

- (7) for curing the stigmata of epidermal and/or dermal atrophy induced by local or systemic corticosteroids, or other form of cutaneous atrophy, or
- (8) for the curative treatment of cicatrization disorders, for repairing stretch marks, or for promoting cicatrization, or
- (9) for combating disorders of sebaceous functioning, or
- (10) for the curative treatment of cancerous or precancerous disease states, or
- (11) for the treatment of inflammatory conditions/afflictions, or
- (12) for the treatment of any skin condition/affliction of viral origin, or
- (13) for the curative treatment of alopecia, or
- (14) for the treatment of dermatological conditions/afflictions manifesting an immunological component, or
- (15) for the treatment of skin disorders caused by exposure to UV radiation, or
- (16) for the treatment of dermatological conditions/afflictions associated with inflammation or infection of the tissues surrounding the hair follicles, or
- (17) for accelerating or promoting hair loss, comprising topically applying onto the skin, scalp and/or hair of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical

oil-in-water emulsion comprising [including] a discontinuous fatty phase dispersed in a continuous aqueous phase and further comprising an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B), wherein [therefor], said at least one biologically active agent (A) is [being non-solubilized therein] in micronized particulate state and is non-solubilized in said emulsion, at least 80%, numerically, of said micronized particles have [having] diameters ranging from 1 to 10 μm and at least 50%, also numerically, having diameters of less than 5 μm , and further wherein said at least one biologically active agent (A) comprises an agent which modulates skin differentiation and/or proliferation and/or pigmentation, an antibacterial agent, an antiparasitic agent, an antifungal agent, an antibiotic, a steroidal anti-inflammatory agent, a non-steroidal anti-inflammatory agent, an anaesthetic, an anti-pruriginous agent, an antiviral agent, a keratolytic agent, a free-radical scavenger, an antiseborrhoeic agent, an antidandruff agent, an anti-acne agent, an antimetabolite, an agent for combating hair loss and for promoting hair growth or vice versa, an antiseptic, or mixture thereof.

42. (Previously Amended) The regime/regimen as defined by Claim 41, comprising curatively treating acne.

43. (Currently Amended) The regime/regimen as defined by Claim 41 [1], said at least one biologically active agent (A) comprising an agent which modulates proliferation and/or differentiation, an antibiotic, an antibacterial agent, an antifungal agent, an antiparasitic agent, or mixture thereof.

44. Withdrawn.

45. Withdrawn.

46. Withdrawn.

47. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 1, having a pH ranging from 5 to 7.

48. (Original) The topically applicable cosmetic/pharmaceutical O/W emulsion as defined by Claim 47, having a pH ranging from 5 to 6.

49. (Currently Amended) A regime or regimen [regiment] for therapeutically treating inflammation or infection of the skin tissue surrounding hair follicles, comprising topically applying onto this skin tissue of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical oil-in-water emulsion comprising [including] a

discontinuous fatty phase dispersed in a continuous aqueous phase and further comprising an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B), wherein [therefor,] said at least one biologically active agent (A) is [being non-solubilized therein] in micronized particulate state and is non-solubilized in said emulsion, at least 80%, numerically, of said micronized particles have [having] diameters ranging from 1 to 10 μm and at least 50%, also numerically, having diameters of less than 5 μm , and further wherein said at least one biologically active agent (A) comprises an agent which modulates skin differentiation and/or proliferation and/or pigmentation, an antibacterial agent, an antiparasitic agent, an antifungal agent, an antibiotic, a steroidal anti-inflammatory agent, a non-steroidal anti-inflammatory agent, an anaesthetic, an anti-pruriginous agent, an antiviral agent, a keratolytic agent, a free-radical scavenger, an antiseborrhoeic agent, an antidandruff agent, an anti-acne agent, an antimetabolite, an agent for combating hair loss and for promoting hair growth or vice versa, an antiseptic, or mixture thereof.

50. (Currently Amended) A regime or regimen:

- (1) for treating common acne, comedones, polymorphonuclear leukocytes, rosacea, nodulocystic acne, acne conglobata, senile acne and secondary acne, or solar, medication-related or occupational acne, or

- (2) for treating ichtyosis, an ichtyosiform state, Darier's disease, palmoplantar keratoderma, leukoplasia, a leukoplasiform state, or cutaneous or mucous (buccal) lichen, or
- (3) for treating all forms of psoriasis, whether cutaneous, mucous or unguial psoriasis, psoriatic rheumatism, cutaneous atopy, eczema, respiratory atopy, gingival hypertrophy, or for treating rosacea, or
- (4) for treating common warts, flat warts, verruciform epidermodysplasia, oral or florid papillomatoses or proliferations induced by ultraviolet radiation, basocellular or spinocellular epithelioma, or
- (5) for treating bullosis or a collagen disease state, or
- (6) for repairing or combating aging of the skin, whether photoinduced or chronological aging, or for reducing pigmentations and actinic keratosis, or any pathology associated with chronological or actinic aging, or
- (7) for curing the stigmata of epidermal and/or dermal atrophy induced by local or systemic corticosteroids, or other form of cutaneous atrophy, or
- (8) for the curative treatment of cicatrization disorders, for repairing stretch marks, or for promoting cicatrization, or
- (9) for combating acneic hyperseborrhoea or simple seborrhoea, or

- (10) for the curative treatment of cancerous or precancerous disease states, or
- (11) for the treatment of arthritis, or
- (12) for the treatment of any skin condition/affliction of viral origin, or
- (13) for the curative treatment of alopecia, or
- (14) for the treatment of dermatological conditions/afflictions manifesting an immunological component, or
- (15) for the treatment of skin disorders caused by exposure to UV radiation, or
- (16) for the treatment of colonization or microbial infection, impetigo, seborrhoeic dermatitis, folliculitis, sycosis barbae, or
- (17) for accelerating or promoting hair loss, comprising topically applying onto the skin, scalp and/or hair of a candidate subject in need of such treatment, for such period of time as required to elicit the desired biological response, a topically applicable cosmetic/pharmaceutical oil-in-water emulsion comprising [including] a discontinuous fatty phase dispersed in a continuous aqueous phase and further comprising an effective amount of at least one thus-biologically active agent (A) and an effective amount of an emulsifying system (B), wherein [therefor,] said at least one biologically active agent (A) is [being non-solubilized therein] in micronized particulate state and is non-solubilized in said emulsion, at least 80%, numerically, of said

micronized particles have [having] diameters ranging from 1 to 10 μm and at least 50%, also numerically, having diameters of less than $5 \mu\text{m}$, and further wherein said at least one biologically active agent (A) comprises an agent which modulates skin differentiation and/or proliferation and/or pigmentation, an antibacterial agent, an antiparasitic agent, an antifungal agent, an antibiotic, a steroidal anti-inflammatory agent, a non-steroidal anti-inflammatory agent, an anaesthetic, an anti-pruriginous agent, an antiviral agent, a keratolytic agent, a free-radical scavenger, an antiseborrhoeic agent, an antidandruff agent, an anti-acne agent, an antimetabolite, an agent for combating hair loss and for promoting hair growth or vice versa, an antiseptic, or mixture thereof.